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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,206	12/01/2003	Stephen D. Barrett	PC20520A	4492
28940	7590	01/23/2006	EXAMINER	
AGOURON PHARMACEUTICALS, INC.			BARKER, MICHAEL P	
10777 SCIENCE CENTER DRIVE			ART UNIT	
SAN DIEGO, CA 92121			PAPER NUMBER	

1626

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/725,206	Applicant(s) BARRETT ET AL.	
	Examiner Michael P. Barker	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5 is/are rejected.
- 7) ☒ Claim(s) 2-4 and 6-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

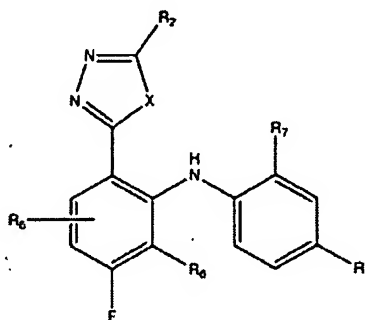
- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/26/04; 9/19/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

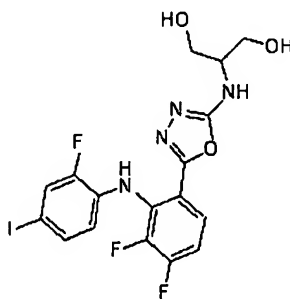
Claims 1-23 are pending in the instant application. **Claims 19-23** are withdrawn as being drawn to nonelected subject matter.

Response to Restriction

Applicants' election without traverse of **Group I, Claims 1-18**, drawn to compounds



represented by the general formula, , and specific compound of



Example 154, p. 86 of the Specification, , classified in class 548, subclass 133, is acknowledged.

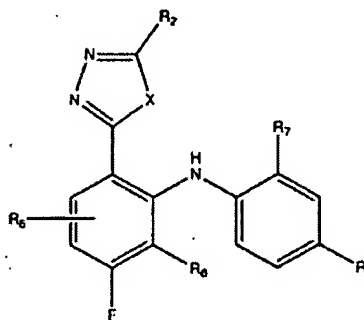
The inventions of Groups I and II are independent and distinct because there is no patentable coaction between the Groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized as divergent in subject matter requiring different search strategies for each group. Moreover, the Examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is burdensome to the Examiner. Thus, the restriction set forth October 14, 2005 is deemed proper.

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As stated in the restriction requirement, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound and examination will then proceed on the elected compound and the entire scope of the invention encompassing the elected compound as defined by common classification.

Regarding requests for rejoinder, as stated in the restriction requirement, rejoinder will be permitted when a product claim is found allowable and then the withdrawn process or methods claims which depend from or otherwise include all limitations of an allowed product claim will be rejoined.

The Scope of the Elected Subject Matter (prior art examined as follows):



Compounds represented by the general formula, , depicted in

Claim 1, wherein:

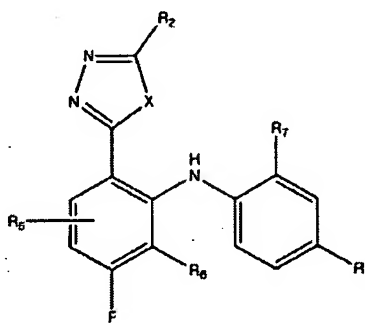
- R_1 is as defined;
- R_2 is NHR_3 ;
- R_3 is as defined except where R_3 contains a heterocyclic ring (for the purposes of this initial search, when R_3 is a heterocyclic group was not searched);
- R_4 - R_7 , m , and n are as defined.

The scope of Applicant's independent invention, set forth in Group I, encompasses all compounds within the scope of the claims of Group I **which fall into the same class as the**

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elected compound. Regarding the scope of compounds set forth above, these compounds are free of prior art and are drawn to allowable subject matter. Amendments to the claims in order to conform with the scope set forth above and cancellation of nonelected subject matter will put Applicant's claimed invention in condition for allowance. Applicant preserves the right to file divisional applications on the remaining subject matter. Because the abovementioned scope of compounds, drawn around Applicant's elected species, is free of the prior art, the search was expanded (below).

The Scope of the Elected Subject Matter (prior art expanded and examined as follows):



Compounds represented by the genus, , depicted in **Claim 1**,

wherein:

- **R₁-R₇** are as defined;
- **X** is as defined;
- **m** and **n** are as defined.

Regarding the scope of compounds set forth above, these compounds are not free of prior art, and rejections are discussed below.

Claim Rejections - 35 USC § 102(e)

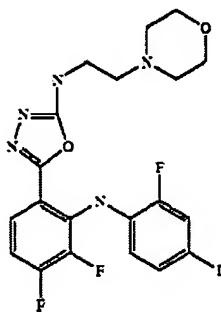
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. US 2003/0224500 (Ohren, et al.) which has an effective priority date of December 21, 2001. Specifically, Ohren, et al. teaches {5-[3,4-difluoro-2-(2-fluoro-4-iodo-phenylamino)-phenyl]-1,3,4-oxadiazol-2-yl}-(2-morpholin-4-yl-ethyl)-amine having the



following chemical structure:

[p. 22, at ¶282], which anticipates Applicant's

broad **Claim 1**, when R_1 is halogen; R_2 is NHR_3 ; R_3 is ; m is 2; R_5 is

hydrogen; R_6 is F; and R_7 is halogen, and further anticipates Applicant's **Claim 5**, in which Applicant specifically lists {5-[3,4-difluoro-2-(2-fluoro-4-iodo-phenylamino)-phenyl]-1,3,4-oxadiazol-2-yl}-(2-morpholin-4-yl-ethyl)-amine (p. 115, lines 10 and 11).

Note

Claim 3 is not being rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. US 2003/0224500 (Ohren, et al.). Applicant's **Claim 3** recites the compound {5-[3,4-difluoro-2-(2-fluoro-4-iodo-phenylamino)-phenyl]-1,3,4-oxadiazol-2-yl}-(2-morpholin-4-yl-propyl)-amine (p. 114, lines 11-13) which differs from

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Ohren's {5-[3,4-difluoro-2-(2-fluoro-4-iodo-phenylamino)-phenyl]-1,3,4-oxadiazol-2-yl}-(2-morpholin-4-yl-ethyl)-amine by one methylene group. Thus, Applicant's compound seems to be merely a homologue of Ohren's disclosed compound.

In light of *In re Henze*, 85 USPQ 261 (1950), one homologue is not such an advance over adjacent members of series as requires invention because chemists knowing the properties of one member of series would in general know what to expect in adjacent members. However, the 103(a) rejection is not being made in this situation because Applicant's disclosure of {5-[3,4-difluoro-2-(2-fluoro-4-iodo-phenylamino)-phenyl]-1,3,4-oxadiazol-2-yl}-(2-morpholin-4-yl-propyl)-amine specifically recites the *hydrochloride salt*. Whereas, Ohren, et al. does not contemplate the salt of {5-[3,4-difluoro-2-(2-fluoro-4-iodo-phenylamino)-phenyl]-1,3,4-oxadiazol-2-yl}-(2-morpholin-4-yl-ethyl)-amine, let alone the specific hydrochloride salt.

Applicant should be aware that the remaining claims of the elected invention which are not rejected are free of the prior art. Amendments to the claims to overcome the rejection will put the entirety of Applicant's elected invention, **Claims 1-18**, in condition for allowance, at which time the nonelected invention, **Claims 19-23**, will be rejoined for consideration of patentability on the merits.

Scope of the Nonelected Subject Matter:

As a result of the election and the corresponding scope of the invention identified *supra*, the remaining **Claims 19-23** which are not drawn to the above elected invention are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.

Priority

This application claims benefit of U.S. Provisional Application Nos. 60/509,701, filed October 8, 2003 and 60/435,155, filed 12/20/2002.

Information Disclosure Statement

Applicant's information disclosure statements (IDS), filed on July 26, 2004 and September 19, 2005, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Objections

Claims 19-23 are objected to for containing nonelected subject matter.

Claims 2-23 are objected to for being based on a rejected base claim.

References Cited

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate the copy was not readily available, the copy could not be readily obtained when the Office action was mailed. Should Applicant desire a copy of such a provisional application, Applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless Applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not

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readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM.

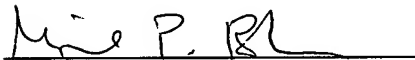
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

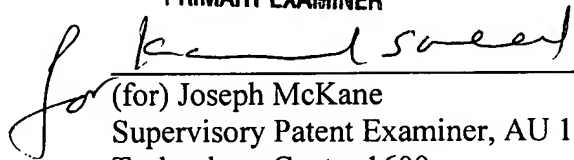
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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